REMARKS

Applicants have amended claim 1 to incorporate the limits of claims 6 and 18. In light of this, claims 6 and 18 have been cancelled. In addition, Applicants have amended claims 7,26-28 and 31 to reflect changes in dependency. Applicants have amended claim 2 and cancelled claim 3 as described below. Applicants have also cancelled claims 32 and 33 and newly added claim 34. No new matter was added by virtue of any of these amendments or the newly presented claim. Thus, claims 1, 2, 4, 5, 7-15, 17, 19-31 and 34 remain pending in this application.

35 USC §112

The Examiner has rejected claims 2,3,6,7, and 26-31 as failing to comply with the written description requirements of 35 USC §112, second paragraph. Applicants have amended claims 1, 2, 7, 26-28 and 31 as well as deleted claims 3 and 6 in order to correct the insufficiency and, thus, respectfully ask for withdrawal of this rejection.

The Examiner has rejected claims 2 and 3 as being indefinite under 35 USC §112 for insufficient antecedent basis for the phrase "said active agent". Applicants have amended claims 1 and 2 and cancelled claim 3 in order to clarify what is being claimed. Therefore, Applicants respectfully request withdrawal of this rejection.

35 USC §102

The Examiner has rejected claims 1-11, 13-15, 22, 26, 27 and 32 under 35 USC §102(b) as being anticipated by US 5,167,964 to Muhammad et al (hereinafter "Muhammad"). However, in order to anticipate the present invention, the asserted reference must be shown to teach each and every element of the claims. Applicants maintain that Muhammad does not teach (nor even suggest) every element of the present claims and, therefore, cannot be said to anticipate the instant invention. The present claims, as amended, are directed to "[a]n orally dissolving, hard boiled, dosage form useful for transmucosal oral administration of a nicotine active, comprising: a glassy matrix...a water soluble gelling gum...and from

about 0.5mg to about 5 mg of nicotine active per dose, at least 50% of which is delivered via the oral mucosa prior to ingestion into the stomach...". Applicants contend that Muhammad does not teach the present invention as the Muhammad compositions are not formulated to deliver *any* medicament via the oral mucosa.

Muhammad relates to a semi-enteric drug delivery system which comprises an inert core, a first coating layer over the core which comprises a medicament and a second coating layer over the first coating layer comprising a mixture of methacrylic acid copolymer, type C, and povidone in a range of particular ratios. *See Muhammad at abstract.* These semi-enteric drug delivery systems may then be formulated with conventional additives or may be incorporated within a hard or soft confectionery composition. *See Muhammad*, column 8, lines 11-20. It is this hard confectionery composition which the Examiner asserts anticipates the compositions of the present invention. However, Applicants point out that the drug delivery systems of Muhammad are not *in the form of* a hard or soft candy confection, rather they may be *incorporated within* such confection. By formulating the Muhammad compositions in this manner, the compositions of the present invention are not achieved.

Column 3, lines 40-45 of the Muhammad specification, it states, "by carefully controlling the concentration of methacrylic acid copolymer, type C, and povidone in a coating layer, semienteric drug delivery systems can be prepared to provide a controlled and sustained release of medicament in the stomach and the upper parts of the small intestine. Further, at column 2, lines 27-31 in describing the advantages of the present invention, Muhammad explains that it would be advantageous to provide "a semi-enteric drug delivery system which would partially release medicament in the stomach for immediate release and thereafter release additional medicament in the intestines for delayed release".

Mere subsequent incorporation of this type of drug delivery systems within a hard candy confection formulation will *not* provide a composition which delivers at least 50% of a nicotine active to the oral mucosa prior to dissolution in the mouth and subsequent ingestion as in the present invention. As the semi-enteric drug delivery systems of Muhammad are formulated to provide release of drug in the

stomach and intestines, there can be no such release of active within the oral cavity. In the present invention, it is the glassy matrix and water soluble gum composition which provides the release rate of the nicotine to the oral mucosa and, thus, the oral absorption of nicotine prior to ingestion. Because Muhammad does not teach each and every element of the claimed invention, it cannot be said that Muhammad anticipates the claimed invention.

Therefore, Applicants respectfully request that the Examiner's rejections based on Muhammad pursuant to 35 USC §102 be withdrawn.

35 USC §103

The Examiner rejects claim 23 and 24 under 35 USC §103 (a) as being rendered obvious by Muhammad. The Examiner further rejects claims 12, 19-21 and 25 under 35 USC §103(a) as being obvious in light of Muhammad in view of Rapp et al. (US 6,180,143 B1, hereinafter "Rapp") or Burnick et al. (US2003/0017202 A1, hereinafter "Burnick"). Applicants maintain that Muhammad, taken alone or in combination with either Rapp or Burnick does not render claims 12, 19-21 or 25 obvious. In addition, the Examiner newly rejects claims 17,18 and 26-31 under 35 USC §103(a) as being obvious in light of Muhammad in view of Santus (US 6,280,761, hereinafter "Santus"). Similarly, Applications maintain that the combination of Muhammad and Santus do not achieve each and every element of the claimed invention.

For the reasons stated above, Applicants believe that Muhammad does not teach each and every element of the claimed invention. Specifically, Muhammad does not disclose to "[a]n orally dissolving, hard boiled, dosage form useful for transmucosal oral administration of a nicotine active, comprising: a glassy matrix...a water soluble gelling gum...and from about 0.5mg to about 5 mg of nicotine active per dose, at least 50% of which is delivered via the oral mucosa prior to ingestion into the stomach...". Similarly, Muhammad cannot be said to suggest each and every element of the claimed invention as the focus in Muhammad is to provide semi-enteric formulations with partial active delivery in the stomach and partial active delivery in the intestines. There is no motivation to modify the

teaching of Muhammad to ensure that any amount of a nicotine active is delivered via the oral mucosa prior to ingestion into the stomach as Muhammad focuses on the delivery of a medicament to the stomach and small intestines.

The Examiner states that "the same compositions would exhibit the same characteristics when placed in the same/similar environment". However, this completely dismisses the differences Applicants point out between the present invention and that of Muhammad. In particular, Applicants point to the distinction that Muhammad's drug delivery formulations *can be incorporated within* a hard candy confection but that the confection itself is not the drug delivery system. In other words, the present inventions are formulated such that the glassy matrix and water soluble gum component serve as the drug delivery "system" providing nicotine release to the oral mucosa prior to ingestion, in stark contrast to the formulations of Muhammad which rely on stomach and intestinal delivery.

The Examiner further relies on Rapp and Burnick for the principle that sweetening agents, such as ISOMALT, are known for use in nicotine formulations. Rapp relates to chewing gum compositions which may comprise 1,1-GPS alone or in combination with other sweeteners. Such sweeteners are incorporated into the Rapp compositions to increase flexibility of the gum and prevent drying out of the gum during storage. Burnick relates to an oral dosage form comprising a soft core encased within a brittle shell coating that also my include sweeteners of the type described above.

Clearly, neither Rapp nor Burnick relates to an oral dosage form comprising a glassy matrix of a non-hygroscopic sugar alcohol which substantially contains an active agent therein, as a glassy matrix would not provide an acceptable chewing gum or chewable soft core composition. Thus the combination of either of these references with Muhammad still would not result in the compositions of the present invention, in particular, "[a]n orally dissolving, hard boiled, dosage form useful for transmucosal oral administration of a nicotine active, comprising: a glassy matrix...a water soluble gelling gum...and from about 0.5mg to about 5 mg of nicotine active per dose, at least 50% of which is delivered via the oral mucosa prior to ingestion into the stomach...".

Finally, the Examiner relies on Santus for the proposition that various types of nicotine are known in the art and that a nicotine lozenge may be useful for smoking cessation and, thus, craving relief. However, Applicants assert that the compositions of the present invention are not obvious in light of Muhammad, and therefore, the methods of using those compositions in the manner described is also not obvious, even in light of the teachings of Santus.

Therefore, Applicants respectfully request that the Examiner's rejections based on 35 USC §103(a) in light of Muhammad in combination with Rapp, Burnick, or Santus be withdrawn.

In light of the amendments submitted herewith and the accompanying remarks, Applicants believe that all objections and rejections raised by the Examiner have been addressed. Thus, Applicants respectfully request withdrawal of the rejections under 35 USC §112, §102 and §103 and allowance of all claims that remain pending.

Respectfully submitted,

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